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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,549	11/21/2001	Gyula Vigh	LIFT-020/01US	2580

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EXAMINER
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OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

09/990,549

Applicant(s)

VIGH, GYULA

Examiner

Kaj K. Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-39 and 42-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-39 and 42-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. .  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 27-29, 39-41 and 43-53 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bier et al (USP 4,204,929) with or without evidence from Martin et al (USP 4,243,507).

3. Bier discloses an isoelectric gateway for altering the composition of a sample that comprises a number of ion-permeable barriers 52-60 any number of which would read on the specified first and second ion-permeable barriers that are a predetermined distance apart from each other (col. 8, ll. 11-51). Between each of the various ion-permeable barriers are isoelectric substances (col. 1, ll. 28-46). With respect to the ion-permeable barriers substantially retaining the isoelectric substances between the barriers, this would appear to be an inherent feature of any isoelectric focusing apparatus including the apparatus of Bier. In particular, isoelectric focusing relies on the establishment of a gradient where each chamber between the ion permeable barriers has a characteristic pH value, which is established and maintained by the presence of an isoelectric substance having a characteristic pI value. See col. 1, ll. 28-46. Because the pH in each of the chambers remains substantially constant (see table I) and because the isoelectric substances will remain at a pH value that matches the substances pI value, the isoelectric substance will remain substantially between two given ion permeable barriers, giving the term

“substantially” its broadest reasonable interpretation. See also col. 4, ll. 4-6 and col. 5, ll. 38-42 where Bier teaches away from any convective flow. Bier also does not disclose binding the isoelectric substances to the ion permeable barriers thereby meeting those limitations as well.

4. With respect to the new limitations requiring the isoelectric substance to be “stationary”, the various isoelectric substances disclosed by Bier would appear to be stationary in the sense that the substances would cease to flow across the various barriers once the appropriate pH gradient has been established. See table I where a stable pH gradient is established prior to the introduction of the sample. Martin evidences that once an isoelectric substance reaches its isoelectric point, it remains stationary (“stationary” in the sense of not moving across the barriers anymore even though the fluid is still moving through the compartments). See col. 4, ll. 62-66 and col. 6, ll. 5-15. Hence, the equilibrated device of Bier inherently has “stationary” isoelectric substances giving the claim language its broadest reasonable interpretation. Moreover, even if the examiner were to interpret the term “stationary” in the specification sense that fluid is not flowed at all, whether or not the fluid is flowed or stationary constitutes the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. For example, when the pump 400 of Bier is not activated, the isoelectric substances would be stationary. Hence, any time the device is not being actively used, all the isoelectric substances in the device would be stationary and would meet this new claim limitation. Alternatively, Bier already recognized that IEF instruments relying on stationary isoelectric substances were already old in the art. See col. 1, l. 59 through col. 2, l. 2. One possessing ordinary skill in the art would recognize that the device of Bier could be utilized without any fluid flow, because the prior art recognized that fluid flow was not necessary for

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isoelectric focusing. It has been generally recognized that taking a step back in the art requires only routine skill in the art. The examiner would note that there doesn't appear to be any criticality or preference for the use of stationary versus flowing fluid in applicant's own disclosure. See p. 6, ll. 26-28, p. 6, ll. 6-7 and p. 8, ll. 20-22.

5. With respect to the remaining limitations of the claims, please see the previous office actions.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 30 and 32 (and claims 27-29, 39-41 and 43-53 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Bier in view of Speicher et al (USP 6,638,408). Speicher is a new reference being relied on for the first time with this office action.

8. Bier set forth all the limitations of claim 30, but did not explicitly disclose the use of a gel membrane as the ion-permeable barrier. Speicher teaches in an alternate IEF device the use of an ion permeable barriers constructed out of gels. See col. 5, ll. 18-35. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Speicher for the apparatus of Bier because the substitution of one known ion permeable barrier for another barrier requires only routine skill in the art.

9. With respect to claim 32, see Speicher col. 6, ll. 4-17 and 62-67.

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10. With respect to claims 27-29, 39-41 and 43-53 in the alternative, even if the examiner were to interpret the “stationary” limitation as requiring no fluid movement whatsoever (i.e. to not read on the “stationary” in the manner Martin did) and as being more than just the intended use of the device, Speicher teaches that it is unnecessary to recycle the fluid placed in the various chambers in order to get the desired isoelectric separation. In particular, Speicher teaches the use of a single port and states that any desired fluid agitation can be provided by either a stirring bar or by rotating the entire device. See col. 7, ll. 18-39. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Speicher and not provide for flowing isoelectric substances for Bier in order to avoid the expense and complexity required for a recirculating device. See Speicher, col. 2, ll. 17-26. Again, the examiner would note that there doesn’t appear to be any criticality or preference for the use of stationary fluid versus flowing or recirculated fluid in the applicant’s own disclosure. See p. 6, ll. 26-28, p. 6, ll. 6-7 and p. 8, ll. 20-22.

11. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bier ‘929 or Bier in view of Speicher in further view of Perry et al (USP 5,087,338).

12. Bier or Bier and Speicher set forth all the limitations of the claim, but did not explicitly recite the use of the set forth groups. Perry teaches in an alternate electrophoresis apparatus that suitable membranes can be constructed from cellulose esters and polysulfones (col. 7, ll. 60-65). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Perry for the apparatus of Bier or Bier and Speicher because the substitution of one known membrane material for another requires only routine skill in the art.

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13. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bier '929 or Bier in view of Speicher in further view of Dubrow (USP 5,164,055).

14. With respect to claim 33, Bier or Bier and Speicher set forth all the limitations of the claim, but did not explicitly recite the use of a frit for forming ion-permeable barriers. Dubrow teaches in an alternate isoelectric focusing apparatus that glass frits are a known material for controlling fluid movement across a barrier (col. 4, ll. 3-5 and col. 10, ll. 52-62). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Dubrow for the apparatus of Bier or Bier and Speicher because frits are a known barrier material and the substitution of one known barrier material for another requires only routine skill in the art.

15. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bier '929 or Bier in view of Speicher in further view of Martin et al (USP 4,243,507).

16. Bier or Bier and Speicher set forth all the limitations of the claim, but did not explicitly recite the use of an isoelectric substance that is a combination of a weak acid and strong base (or strong acid and weak base). Martin discloses in an alternate isoelectric device that the most convenient means for achieving various pHs for each isoelectric compartment is to utilized a combination of a weak acid and strong base (or a strong acid and weak base) (col. 4, ll. 15-29). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Martin for the apparatus of Bier or Bier and Speicher because the set forth acid and base combinations are the most convenient means for achieving selective pHs for isoelectric compartments.

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17. Claims 35-38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bier or Bier in view of Speicher in view of either Hearn et al (USP 4,279,724) or Söderberg (USP 4,334,972).

18. With respect to claim 35, Bier or Bier and Speicher set forth all the limitations of the claim, but did not explicitly recite the use of polymers containing amino and at least one other of the set forth groups. Söderberg teaches that Ampholine (i.e. the material utilized by Bier (col. 1, ll. 36-39)) comprises polymers of carboxylated imines. See col. 1, ll. 20-27. Carboxylated imines would comprise both amino groups and carboxyl groups thereby meeting the claim limitation. Hearn also teaches that Ampholine comprises polyamino-polycarboxylic acids. See col. 1, ll. 23-40. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teachings of either Söderberg or Hearn for the ampholyte of Bier or Bier and Speicher because Bier explicitly suggested using the specified ampholyte.

19. With respect to claims 36-38, both Söderberg and Hearn also taught that the gap between pK and pI value should be as low as possible, including less than 1 pH unit. See col. 2, ll. 52-62 and col. 1, ll. 23-30 for Söderberg and Hearn respectively.

20. With respect to claim 42, a polyamino-polycarboxylic acid would presumably meet the broadly defined "non-natural amino acid" because any monomer or polymer containing both amino and carboxylate groups would constitute an amino acid.

21. Claims 35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bier or Bier in view of Speicher in view of WO 92/15,870 (hereafter "WO '870").

22. With respect to claim 35, Bier or Bier and Speicher set forth all the limitations of the claim but did not explicitly recite the use of an isoelectric substance from the claimed group.



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However, WO '870 teaches that polyamino- polycarboxylic acid is a conventional material utilized for forming an isoelectric substance (p. 2, l. 25 through p. 3, l. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '870 for the apparatus of Bier or Bier and Speicher because the substitution of one known isoelectric substance for another requires only routine skill in the art.

23. With respect to claim 42, a polyamino-polycarboxylic acid would presumably meet the broadly defined "non-natural amino acid" because any monomer or polymer containing both amino and carboxylate groups would constitute an amino acid.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Friday from 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 3, 2007

A handwritten signature in black ink, appearing to read 'Kaj K. Olsen', with a stylized, flowing script.

**KAJ K. OLSEN**  
**PRIMARY EXAMINER**